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Treatment of periodontitis non-surgically by topical melatonin and vitamin C

Submission date
20/09/2024

Recruitment status
No longer recruiting

Registration date
02/10/2024

Overall study status
Completed

Last Edited
08/01/2025

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Background and study aims
Melatonin can eliminate free radicals and this function can be improved by vitamin C. The aim of this study was to investigate the effect of the use of melatonin and vitamin C in the non-surgical treatment of chronic periodontitis (gum disease).

Who can participate?
Patients aged 18-65 years with chronic periodontitis

What does the study involve?
Participants are randomly allocated into three groups: non-surgical periodontal therapy (NSPT); NSPT with melatonin; and NSPT with melatonin and vitamin C. Assessments were done at the start of the study and at 1 week, 1 month and 3 months after therapy.

What are the possible benefits and risks of participating?
Regarding benefits, there may be improvement and healing of periodontitis and overall oral health and quality of life. Regarding risk, as it is a clinical trial it may cause discomfort to the participants since it requires follow-ups.

Where is the study run from?
Azadi Dental Center (Iraq)

When is the study starting and how long is expected to run for?
December 2022 to August 2024

Who is funding the study?
Hawler Medical University (Iraq)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Evaluation of the effect of topically applied melatonin and vitamin C in non-surgical treatment of chronic periodontitis

Study objectives
This study was designed to test the hypothesis that topical application of melatonin and vitamin C adjunct to non-surgical periodontal therapy will produce a better impact on probing depth, and clinical attachment loss than melatonin with non-surgical periodontal therapy (NSPT) and NSPT alone.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 14/02/2023, Research Protocol Ethics Committee (Kurdistan Higher Council of Medical Specialties, Erbil, 4400, Iraq; +964 (0)7503319493; president.office@khcms.edu.krd), ref: 56

Study design
Single-center interventional triple-blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format

Health condition(s) or problem(s) studied
Localized chronic periodontitis with pocket depth ≥5 mm

Interventions
The intra-oral examination assessed gingival inflammation using the Gingival Index (GI), as well as measuring Probing Depth (PD) and Clinical Attachment Loss (CAL). The PD was measured from the pocket base to the gingival crest, while CAL was measured from the pocket base to the cemento-enamel junction. These measurements were taken using a William's periodontal probe (MEDESY, Maniago, Italy). For each index tooth, measurements were recorded at four surfaces: mid-buccal/facial, mid-lingual/palatal, mesio-buccal, and disto-buccal. Participants were randomly divided into three groups using computer software: placebo, melatonin, and melatonin with vitamin C. Initial clinical parameters were recorded pre-treatment. All participants received full mouth scaling and root planning (SRP) using an ultrasonic device (DTE, D2 LED, Guilin Woodpecker Medical Instruments Co Ltd, Guilin, China), and Gracey periodontal curettes (Hu-Fridey Instruments, Chicago, IL, USA), followed by coronal polishing. Patients returned after 7 days for local drug application, which continued weekly for four weeks. The placebo group (33 patients) received 1 ml of 1% placebo gel. The melatonin group (33 patients) received 1 ml of 5% melatonin gel. The melatonin and vitamin C group (34 patients) received 1 ml of 250 mg vitamin C liquid for 5 minutes, followed by 1 ml of melatonin gel. Applications used disposable syringes with blunt needles. Patients were instructed not to rinse or eat for 30 minutes after application. A dental assistant managed daily arrangements to maintain researcher blindness.

Clinical measurements were taken four times: pre-treatment (baseline), 1 week post-therapy, 1 month post-intervention, and 3 months post-treatment. Measurements included Gingival Index (GI), Clinical Attachment Loss (CAL), and Probing Depth (PD). A single examiner (the researcher) conducted all clinical examinations.

The researcher, participants, and statistician were blinded to treatment types.

Intervention Type
Drug

Pharmaceutical study type(s)
Not Applicable

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Melatonin gel, vitamin C solution

Primary outcome measure
1. Presence or absence of gingival inflammation, evaluated using Gingival Index (GI) and Periodontal Disease Index (PDI)
2. Probing Depth (PD) (distance from the base of the pocket to the crest of the gingiva)
3. Clinical Attachment Loss (CAL) (distance from the base of the pocket to the cemento-enamel junction)
Measured with William's periodontal probe (MEDESY, Maniago, Italy) at four surfaces per one index tooth (mid-buccal/facial, mid-lingual/palatal, mesio-buccal and desto-buccal)

Measured four times during the study, the first measurement was recorded at baseline before SRP was done (pre-treatment record), then the second record 1 week after the therapy, the third record 1 month after the intervention and after 3 months of the treatment the patients were recalled again to record clinical measures (GI, CAL and PD). The clinical examination was carried out by a single examiner who was the researcher. All researchers, the participants and statisticians were blind to the type of treatment.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
22/12/2022

Completion date
01/08/2024

Eligibility

Key inclusion criteria
1. Systematically healthy patients with localized chronic periodontitis
2. Aged 18-65 years
3. Pocket depths ≥5 mm

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
100

Total final enrolment
88

Key exclusion criteria
1. Pregnant and lactating women
2. Smokers
3. Those who had used non-steroidal anti-inflammatory drugs, mouthwash or vitamin supplements within 3 months prior to the study

Date of first enrolment
01/08/2023

Date of final enrolment
26/11/2023

Locations

Countries of recruitment
Iraq

Study participating centre
Azadi Dental Center
Periodontics Department
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Sponsor information

Organisation
Hawler Medical University

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Sponsor type
Research council

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ROR
https://ror.org/02a6g3h39

Funder(s)

Funder type
University/education

Funder Name
Hawler Medical University

Alternative Name(s)
Zankoy Hewlêrî Pizîşkî, , , HMU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Iraq

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study will be included in the subsequent results publication.

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		31/12/2024	08/01/2025	Yes	No